UNITED STATES DISTRICT COURT
for the
DISTRICT OF NEW JERSEY

CHAYA GROSSBAUM and MENACHEM GROSSBAUM, her spouse, individually and as *guardians ad litem* of the infant ROSIE GROSSBAUM,	
Plaintiffs,	CIVIL ACTION NO. 07-CV-1359 (GEB)
vs.	
GENESIS GENETICS INSTITUTE, LLC, of the State of Michigan, MARK R. HUGHES, NEW YORK UNIVERSITY SCHOOL OF MEDICINE and NEW YORK UNIVERSITY HOSPITALS CENTER, both corporations in the State of NEW YORK, ABC CORPS. 1-10, JOHN DOES 1-10,	PLAINTIFFS REQUEST ORAL ARGUMENT
Defendants.	

PLAINTIFFS' BRIEF IN OPPOSITION TO DEFENDANTS' MOTIONS FOR SUMMARY JUDGMENT AND TO BAR EXPERT TESTIMONY

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PRELIMINARY STATEMENT

I.

In these Motions for Summary Judgment the Defendants have stretched the process described in Civil Local Rule 56 beyond reason. Defendants have produced as undisputed facts: opinions of their own experts, even those opinions that are disputed by Plaintiffs' experts; abstracts of learned treatises (not even the full text) which were not mentioned by any expert or provided in discovery; opinions of Defendant's counsel on medical issues, which were never the subject of expert testimony; selective references to the medical history, on one such occasion failing to mention a significant part of Defendant, Genesis Genetics', laboratory record—the final report to NYU—which contained significant admissions as to the unreliability of the Plaintiffs' genetic analysis with the excuse that the document is "hotly contested." (Footnote on Page 6 of Genesis SUF[1]) In addition, the Defendant Genesis Genetics claims that the Plaintiff should have undergone invasive prenatal testing for the sole purpose of determining whether they may want to bring a lawsuit within the statute of limitations related to any alleged negligence in the IVF-PGD process. (See Def. Genesis' brief at Page 31.)

[1] Statements of Undisputed Material Facts are hereinafter referred to as "SUF."

In addition, Defendant NYU's Motion to Strike Plaintiffs' liability expert is almost unbelievable in that the *curriculum vitaes* of these individuals document their pre-eminence in the clinical and laboratory practice of the science of genetics in eliminating hereditary diseases. (Cutting report at NYU Exh. N.)

II.

This lawsuit and the issues it projects is one of the first in the nation concerning preimplantation genetic diagnosis. There is not a single reported case arising out of a federal court in the national reporter system involving PGD, and only a single case reported in the State Court of California (incidentally involving the Defendant, Dr. Mark R. Hughes). Notwithstanding the newness of the science, PGD is mainstream genetics involving highly respected medical centers throughout the world and has produced a plethora of peer review articles in journals and treatises on reproductive medicine as will be seen from the material submitted herein. (See Bibliography to articles at Pl. Exh. 4 and Exh. 5.)

COUNTER-STATEMENT OF FACTS

PLAINTIFFS' NEW JERSEY CONNECTION

Defendants', Genesis Genetics and Mark Hughes' [hereinafter collectively "Genesis"], recount of Plaintiffs' circumstance as Orthodox Jews and their plans to marry and start a family each burdened with recessive gene mutations for cystic fibrosis is

not disputed in general terms. (For a slightly more detailed history, see Declaration of Chaya Grossbaum; Pl. Exh. 3.) However, Genesis' limited reference to Plaintiffs' move to New Jersey after the birth of the child with the implied suggestion that the Plaintiffs may have been "forum shopping" belies the extensive connection with New Jersey reported in Pl. SUF No. 7.

Chaya Grossbaum was born and raised in New Jersey, met her future husband in New Jersey and after marriage, temporarily moved to the "Big City" until they would be ready to settle down to raise a family, and return to her family locale in Morristown, New Jersey. Plans to move to New Jersey and make it their domicile were implemented long before they became aware that their child of two weeks, born in a New Jersey hospital, was affected with cystic fibrosis. Prenatal medical care was provided by Denville Midwives located in Boonton, New Jersey and a New Jersey pediatrician was engaged prior to the delivery. And long before they had any idea as to the merits of the claims put forth in this litigation, the baby's treatment for cystic fibrosis had begun at Morristown Memorial Hospital's Cystic Fibrosis Center. The Plaintiffs move to New Jersey followed the baby's birth by approximately five months.

GENESIS: A NATIONAL, EVEN INTERNATIONAL BUSINESS

The Defendant Genesis' description of its operation as being an entirely Michigan "place of business" belies the reach

of Genesis' business operations. Although the laboratory studies take place in Michigan, the genetic counseling and laboratory services are conducted "with patients of fertility clinics," as described in Dr. Hughes' biography in July 2004 (when the Grossbaum studies were made), "all over the world." (See Pl. Exh. 17.) Moreover, Genesis' website advertises the national reach of the lab's consulting business, listing Genesis' "partners" in New Jersey to be no less than four fertility clinics. [Emphasis supplied.] (See Pl. Exh. 13.)

ROSIE GROSSBAUM: A PRODUCT OF UNPROTECTED SEX?

Defendant Genesis' factual claims regarding the Grossbaums' disregard of appropriate standards of abstinence during the in-vitro fertilization process and the impact on this case are hardly undisputed, and based on science that only appears from the opinions of the defense counsel. The Defendant's factual allegation also fails because:

(1) It does not describe the standard for sexual abstinence communicated to the Plaintiffs by NYU;

(2) Defendant Genesis' claim that the Plaintiffs should have abstained from sexual intercourse "during the fertility treatment cycle" without defining the cycle or referring to any expert opinion criticizing the Plaintiffs' conduct in this case;

(3) It misrepresents the testimony of Chaya Grossbaum about the timing of sexual intercourse; and

(4) It relies on abstracts of learned treatises (and not even the full text) that have neither been qualified nor made applicable to the Plaintiffs. Moreover, there is an attempt to create a failure rate for protected sex with condoms based on the idiosyncrasies of worldwide populations, relating principally to the efficiency of use and not scientific evidence as to the effectiveness of the material used in the manufacture of condoms.

Moreover, the Plaintiffs received special written instructions as to sperm collection method and were provided with special condoms, which were used. (See Pl. Exh. 3 No. 10.)

Furthermore, Defendant does not explain how pregnancy was accomplished after retrieval since Chaya Grossbaum's eggs were removed. Also, there is a question as to whether blood studies prior to implantation would have revealed an unwanted pregnancy.

MAKING THE GROSSBAUMS GENETIC EXPERTS

Genesis describes the events of the implantation of Embryos No. 7 and No. 8 (as the embryos are designated on the Genesis report to NYU) suggesting that "suitability" of the embryos for IVF was a NYU decision and "the Grossbaums concurred in this decision." (See Genesis SUF No. 24.) To the extent that Genesis suggests that there was any knowledgeable participation in the decision as to the suitability of the embryos by the Grossbaums, this claim grossly misstates their competence in decision making

regarding implantation. This nuance is not insignificant since it is a critical issue as to NYU's standard of care in counseling the Plaintiffs and is a central issue in the case.

A STRAW MAN: THE NUMBER OF LABORATORIES DOING PGD WITH LINKAGE ANALYSIS IN THE UNITED STATES

Genesis' factual statements as to the number of labs that performed PGD in early 2004 as being eight mistakes the record and inaccurately ascribes such conclusion to the testimony of Dr. Charles Strom, Plaintiffs' liability expert. (See Pl. Response to Def. Genesis' SUF No. 62.) Also, the attempt to convey the impression that the technology required to properly test the Grossbaums' embryo cells was evolving clearly is not accurate and is certainly not undisputed. Dr. Charles Strom testified at deposition upon questioning by Mr. Stephen Leuchtman, Michigan counsel for Defendant Genesis:

> Q. And do you agree that by characterizing, again, P.G.D. with duplex [multiplex] P.C.R. as improving, the authors of the article, Goosens, et al., acknowledge that duplex [multiplex] testing with genome markers was still evolving?
>
> A. No.
>
> Q. You think it was settled science at that time?
>
> A. I think the concept of multiplex P.C.R. for the detection of allele dropout was well established by the year 2000 when I left R.G.I. Other people began instituting them in their own programs at that point and the

> Thornhill report was what he had implemented.

(See Strom Dep. 5/4/10 T:38-14 to 39-5; Pl. Exh. 7.)

Moreover, Genesis' claim that "one laboratory, Reproductive Genetics Institute (RGI), performed multiplex (or genetic marker) testing" (see Genesis' brief at Pages 8 to 9) belies Dr. Hughes' own deposition testimony and begs the question: why didn't Genesis Genetics do multiplex (linkage) testing in this case? Or, why didn't Genesis tell the Plaintiffs that their results would be at a higher risk for misdiagnosis? At his first deposition on February 19, 2009, Dr. Hughes, in responding to the question whether he was aware whether the multiplex/linkage testing was done at other laboratories in the United States, stated:

> We were all trying to do it which was why I wanted to have those embryos so we can set genetic phase for the family and do that. …in order to look at polymorphic markers you need to have some way to link the markers to the mutations. …we had the equipment to do it, but we needed to have another sample. So you need a member of the family. This couple had a healthy child or if this couple had an affected child or a sister or brother that were carriers that we could get a sample from, the idea would then be to look at those markers and set what is called genetic phase to determine whether the marker which markers are linked to the mutation.
>
> If they had to go through this another time, we would then try to develop a better test using those genomic markers.

Additional questioning disclosed that he was:

> …perfectly aware of all of that technology.

Dr. Hughes agreed that:

> If the cause of the misdiagnosis was allele dropout, if that was the cause of the problem and if we had a sample that they would give us, that would allow us to use the technology, absolutely it would have helped and we do that routinely now.

(See Pl. SUF at Nos. 11 to 15.)

The only possible interpretation of Dr. Hughes' testimony cited above is that Genesis had the capacity to do multiplex/ linkage analysis on the Grossbaum's embryo cells and just didn't do it, and the defense position reflected in later testimony of Hughes and argued in their brief is a contrivance.

THE OPINIONS OF DEFENDANT GENESIS' EXPERT, DR. KANGPU XU

Genesis, on Summary Judgment, asks the Court to accept the testimony of its expert, Dr. Kangpu Xu, and reject the testimony of Plaintiffs' experts. This appears to this writer to violate every rule relating to the summary judgment process as described by Civil Local Rule 56 – even to the point of making this Defendant's Motion frivolous. The Defendant Genesis is acutely aware, and the Court surely recalls, Plaintiff's appeal from rulings by the Magistrate Judge limiting an investigation into the creation of Dr. Kangpu Xu's expert report. Specifically, Dr. Xu's report was challenged when compared to the Dr. Hughes'

expert report (Pl. Exhs. 20 and 21) by the following allegations that are repeated herein from the District Court application as well as the Mandamus application to the Third Circuit Court of Appeals:

(a) The form and content of the first paragraph of each report is exactly the same, even to the extent of a misplaced comma;

(b) The second paragraph of each report is essentially identical in subject matter, sentence structure and words used;

(c) The third paragraph of Dr. Xu's report, containing his biographical information, is the only paragraph in the entire Xu report that has a "number of grammatical mistakes" which are not present in any other of the 11 paragraphs that make up this report;

(d) The seventh paragraph of the Xu report and the eighth paragraph of the Hughes report are essentially identical;

(e) The ninth paragraph of the Xu report and the 11th paragraph of the Hughes report are essentially identical; and

(f) The tenth paragraph of the Xu report and the 12th paragraph of the Hughes report are essentially identical including the text references.

Moreover, to suggest that Dr. Kangpu Xu's opinions should be understood to support a claim (regardless of its relevancy) that multiplex/linkage testing was not being widely done in 2004 disregards Dr. Xu's admission on deposition. He was specifically asked:

Q. And is it possible that you were doing linkage analysis for cystic fibrosis in early 2004?

A. I don't remember if we did.

Q. Are you able to say definitely that you did not do linkage analysis for cystic fibrosis in the year 2003?

A. No, I can't say definite.

(See Xu. Dep. 5/13/10 T:29-17 to 30-1; Pl. Exh. 18.)

DEFENDANT GENESIS' STATISTICS
FOR RISK OF MISDIAGNOSIS

Genesis' brief makes the bald statement: "the failure rate of single cell PGD was less than 5 percent in early to mid 2004." That is true to the extent that 0.05 percent is less than 5 percent, which is the misdiagnosis rate reported by Dressen, et al, published by the European Society of Human Reproduction and Embryology in Molecular Human Reproduction in 2000 (Pl. Exh. 5) and described by Thornhill (Mayo Clinic) as reducing the risk of ADO to almost nil. (See Pl. SUF No. 10.) Moreover, there is no reference to any statistical reporting on the failure rate offered by the Defendants, either within the records presented from Genesis or any fertility clinic, or the reporting literature. In fact, Dr. Hughes was challenged to support his claim as to the statistical rate for misdiagnosis for single cell cystic fibrosis PCR testing and it was demonstrated that his only knowledge was hearsay and hearsay that could not be ascribed to any single source in which the

credibility could be tested or weighed. (See Hughes Dep. 5/14/10 T:41-6 to 42-15; Exh. 11.)

Permit us to recall for the Court Pl. SUF at No. 10 which reports on the literature in Europe reflecting that with multiplex/linkage analysis, misdiagnosis rate for compound heterozygous mutations (the patients' types) could be reduced to less than 0.05 percent. This information managed to cross the Atlantic and half of the United States to the Mayo Clinic where in 2002 the Thornhill report commented that ADO, the prime problem reported by Hughes and Defendants' experts, was "virtually always detected." (See Pl. Exh. 4 at Page 16.)

For these Defendants to claim that the European experience is not relevant to the standard of care, and the knowledge and information available to the Defendant Genesis, permit us to point out that in his deposition of May 14, 2010, Dr. Hughes indicated that he had just returned from a meeting of the "PGD International Society" in France (the source of the European publications). (See Hughes Dep. 5/14/10 T:42-19 to 42-23; Exh. 11.)

LEGAL ARUGMENT

I.

GENESIS MISTATEMENTS OF LAW

Defendant Genesis' brief misstates the law with respect to:

(a) Seeking to claim that the Plaintiffs' negligence case should be labeled a "wrongful death/wrongful birth" tort and apply Michigan law, which does not recognize such claims;

(b) Failing to recognize that the New Jersey causation law applies "increased risk" principles and not "but for" causation;

(c) Failing to recognize that the standard of care is not defined solely on what other practioners in a certain field do.

A.

"CHOICE OF LAW" RULES

As noted by the brief of Co-Defendant NYU, applying New Jersey choice of law principles as the law of the forum, New Jersey employs the "most significant relationship test." NYU cites a more current statement of principles on the issue than Genesis from the New Jersey Supreme Court in P.V. ex rel. v. Camp Jaycee, 197 N.J. 132, 135-136, 962 Atlantic2d 453, 455 (2008); see also from the New Jersey District Court Agostino v. Quest Diagnostics, Inc., 256 FRD 437, 460-461 (D.N.J. 2009). Applying the principles from the cited cases, the NYU brief clearly recognizes the myriad of relationships stemming from the birth and residence of the baby Rosie and her parents for almost all of their lives in New Jersey to conclude New Jersey law applies. The court should find persuasive the decision in In Re Vioox Products Liability Lit., 239 FRD 450 (Ed. LA 2006) where the court ruled: "the court finds that each plaintiff's home

jurisdiction has a stronger interest in deterring foreign corporation from injuring its citizens and ensuring its citizens are compensated than New Jersey does in deterring its corporate citizens' wrongdoing."

Nevertheless, it is also worthwhile to point out that the Defendant Genesis' attempt to put the wrongful life/wrongful birth labels on Plaintiffs' claims for the purpose of applying Michigan law and defeating the claims should also not be conclusive. While Michigan law does in fact appear to bar wrongful life/wrongful birth claims, Defendants' contention fails to recognize that a careful factual analysis would reveal that the claims of these Plaintiffs do not necessarily involve wrongful life/wrongful birth. All of the wrongful life/wrongful birth cases involve the identification of unhealthy conditions of the fetus in the prenatal state and require an argument that the unhealthy baby should not have been allowed to be born, and the consequences therefrom. As explained in Taylor v. Kurapati, 236 Mich.App. 315, 600 N.W.2d 670 (Mich.App. 1999), which precipitated legislative action, relying significantly on the New Jersey Supreme Court opinion in Gleitman v. Cosgrove, 49 N.J. 22 (1967) (albeit overruled by Berman v. Allan, 80 N.J. 421 (1979)), Michigan law did not allow for abortion and found that it was "impossible for a court to measure their [parents]

damages in being the mother and father of the defective child." (Pg. 343.)

However, with respect to the enacting of the Michigan statute MCL 600.2971 in 2001, the legislative history provided by the Defendant Genesis disclosed that not all defective children born are without recourse. In the House Legislative Analysis Section cited as Exh. 30 to the Genesis SUF, the legislature recognized that the medical advances in fetal surgery may allow for the correction of fetal disability. Negligent performance of that surgery which increased the risk of harm to that fetus and ultimately the baby allowed for a negligence suit since "such a case would not have to be brought under the wrongful life/wrongful birth legal framework."

Likewise, with the scientific advances in PGD where there is a matter of selecting which of the embryos should be used to complete the process of conception for the Plaintiff essentially free of hereditary disease risks, it is merely a medical negligence case and does not necessarily involve decisions of abortion and thus, wrongful birth/wrongful life. As noted from the literature, one of the principal reasons for undergoing the stress and expense of PGD is to avoid abortion. (See Pl. SUF No. 6.) Also, the Plaintiffs were very clear that it was couples like them the experts were writing about. (See Declaration of Chaya Grossbaum at Pl. Exh. 3.) The couple could

have used an unaffected embryo. In any event, these distinctions are clearly mooted by the fact that with respect to "choice of law" rules, New Jersey was the proper law to be applied.

Moreover, the scenario created by Genesis in its argument regarding "classic wrongful birth" claim misstates the facts. The issue is not whether Rosie Grossbaum would never have been born and the Plaintiffs would never had become the parents of a child with cystic fibrosis. The issue is whether Rosie Grossbaum, the product of the union of Chaya and Menachem Grossbaum, would have been a child born from an embryo free of the cystic fibrosis disease. That opportunity existed with IVF, a procedure that preceded the New Jersey decisions in Berman v. Allan, 80 N.J. 421 (1979), and its progeny.

Significantly, in Berman at Page 426 we find:

> As such, this case presents issues different from those involved in malpractice actions where a plaintiff asserts that a defendant's deviation from sound medical practices *increased* the probability that an infant would be born with defects. ...Nor are we here confronted with a situation in which an individual's negligence while a child was in gestation caused what otherwise would have been a normal and healthy child to come into the world in an impaired condition...Here, defendants' alleged negligence neither caused the mongoloid condition nor increased the risk that such a condition would occur. In the words of the Gleitman majority, 'the infant plaintiff [asserts] ... not that [she] should have been born without defects but [rather] that [she] should not have been born at

> all…' In essence, Sharon claims that her very life is 'wrongful.' [Citations omitted.]

In addition to meeting the most significant relationship test, which is prong two of the choice of law analysis, Plaintiffs also suggest that prong one of the analysis, whether there is in fact an actual conflict between Michigan law and New Jersey law, may not exist, would also dictate that the presumption relative to the forum state would also control. Since this is a case of first impression with respect to how both Michigan and New Jersey would treat the legal principles related to the issues presented with PGD, it cannot be certain that there would be a difference between the law of New Jersey and the law of Michigan with respect to the novel issues in this case.

B.

THE STANDARD OF CARE

As mentioned above, Defendants' standard of care definition is classically wrong. By his own admission, described in a "Message" and "Final Report" that Dr. Hughes claims to have sent to NYU on completion of the genetic analysis of the Grossbaum speciman: "We are disappointed with the results given the large number of amplification failures for one of the two alleles." The husband's DNA provided only two of ten amplifications (results) with only "partial DNA. Follow up amniocentesis or

CVS would be essential in this setting." (See Pl. Exh. 9.) This statement further undermines any confidence in Genesis' test results. A request for the remaining embryos by Dr. Hughes can only be understood to relate to multiplex/linkage analysis if the Grossbaums go through another IVF cycle. Dr. Hughes goes on to emphasize in the final report that the poor results could be attributed to allele dropout (ADO). (See Pl. Exh. 10.) The aforementioned problems with the results are an example of why Plaintiffs' experts argue that the failure to do linkage analysis was malpractice. (See reports of Plaintiffs' experts Genesis Exh. 24 and Exh. 25.)

While the limited number of laboratories performing PGD analysis with multiplex/linkage testing may be argued by the Defendant as evidence as to the standard of care, it is by no means conclusive or even relevant, especially since there is no specific evidence that other laboratories, whoever they may be, were doing analysis of compound heterozygous gene mutations for cystic fibrosis. The lack of merit in Defendant's position regarding the significance of whether other laboratories were performing multiplex/linkage analysis is demonstrated by recalling the observation of Justice Oliver Wendell Holmes more than a century ago:

> What is usually done may be evidence of what ought to be done, but what ought to be done is

> fixed by a standard of reasonable prudence, whether it is usually complied with or not.

Texas & Pacific Ry. Co. v. Behymer, 189 U.S. 468; 22 S.Ct. 622; 47 L.Ed. 905 (1903).

Aside from the factual questions arising out of Defendant Hughes' testimony of February 19, 2009, challenging his later claims that Genesis did not have the technological capacity to do linkage/multiplex analysis testing, Defendants' position on standard of care raises many more unanswered questions concerning the alleged incapacity to do that kind of testing. Other than vague references to the march of science, what explanation is given, scientific or otherwise, as to why RGI has been doing linkage/multiplex testing since 2000 and Genesis claimed it could not do that test and further, that the Europeans were doing it all over Europe since 2000 as well. (See also Dreesen, et al at Pl. Exh. 5 and Goosens, et al from Belgium referred to at Hughes Dep. 2/19/09 T:58-15 to 59-2; Pl. Exh. 6.) Defendant Genesis' expert, Dr. Kangpu Xu, stated that "Cornell might have been doing it in 2003" since he couldn't say for sure they weren't. (Xu Dep. 11/23/10 T:29-17 to 30-1; Pl. Exh. 18.) Nowhere has Genesis made it clear as to why Genesis was not able to do linkage/multiplex testing for the Grossbaums other than they failed to request the necessary genetic material from the Grossbaums in order to process that type of testing.

Genesis' failure to perform such testing for the Grossbaums begs the question as to why, especially when others had succeeded not the previous week or previous month, but years before. If Dr. Hughes had been playing Russian roulette with the Plaintiffs, how unconscionable is that? After all, how far is Detroit from Chicago? If RGI-Chicago is the only lab technically skilled enough to perform linkage/multiplex testing, is there not a duty on the part of Genesis and Dr. Hughes to send those Plaintiffs to RGI? It is a well known principle of modern medicine that physicians are required to refer to specialists with greater skill and knowledge, if the specialty is required. See Benevino v. Saydjari, 574 F.2d 676 (2d Cir. 1978). Why should the same duty not have applied to Dr. Hughes and his laboratory, Genesis Genetics Institute?

It appears that Genesis and Dr. Hughes are also trying to use a modern day version of the "locality" rule. That rule, long rejected in New Jersey and throughout the country, advanced the proposition that the standard of care should be measured by the way medicine was practiced in a particular locality, usually rural or in small towns, and away from the big city hospitals, such as New York, Boston, Philadelphia or Baltimore. Courts all over the country have established what has been referred to the "national standard." With Chicago doing it, and the Mayo Clinic doctors writing about it, and international organizations

describing it in learned treatises published by doctors at major European hospitals, how can Genesis and Dr. Hughes argue against using linkage/multiplex testing for compound heterozygous mutations not being the standard of care in 2004?

As noted in Naccarato v. Grob, 384 Mich. 248, 180 N.W.2d 788 (Mich. 1970):

> The reliance of the public upon the skills of a specialist and the wealth and sources of his knowledge are not limited to the geographical area in which he practices. Rather his knowledge is a specialty. He specializes so that he may keep abreast. Any other standard for a specialist would negate the fundamental expectations and purposes of a specialty. The standard of care for a specialist should be that of a reasonable specialist practicing medicine in light of present day scientific knowledge. Therefore, geographical conditions or circumstances control neither the standard of a specialist's care nor the competence of an expert's testimony. (*Id.* at Page 254.)

C.

DEFENDANT GENESIS GENETICS CITES THE WRONG PROXIMATE CAUSE STANDARD

It should not escape the Court with respect to the issue of proximate cause that the Defendant has cited the Court to Gardner v. Pawliw, 150 N.J. 359 (1997). While stating the broadest principles applicable to a medical malpractice case appropriately, the Defendant Genesis failed to address the detailed discussion of proximate cause for which the Gardner opinion stands. The law in Gardner cited by Defendant Genesis

was established more than 50 years ago. What Gardner really stands for is an explanation of the scope of the "modified proximate cause rules." The Supreme Court stated in Gardner:

> We hold that the trial court erroneously precluded the jury from determining whether the obstetrician's failure to perform diagnostic tests increased the risk that plaintiffs' fetus would not survive and whether that increased risk was a substantial factor in causing the fetus's death. (*Id.* at Page 363)

If you interpose the words "cystic fibrosis disease" for "survival and death," this Court should clearly understand the causation issues as represented by the New Jersey law. The issue in the case *sub judice* involves the modified proximate cause principles of "increased risk" which were further described most recently in the New Jersey Supreme Court's decision in Verdicchio v. Ricca, 179 N.J. 1 (2004).

DEFENDANTS ASSERT THAT "PLAINTIFFS CANNOT PROVE THE CAUSATION ELEMENT OF THE WRONGFUL BIRTH/WRONGFUL LIFE": THEY ARE WRONG

Whether labeled wrongful birth or wrongful life, or merely negligence, with informed consent features, the factual distinctions between the case *sub judice* and the wrongful birth and wrongful life cases are material. In the case sub judice, the malpractice alleged is multifaceted. The primary malpractice claim is that Defendant Genesis failed to use appropriate standards in testing the Plaintiffs' embryos for the

presence of the cystic fibrosis compound heterozygous gene mutations, failed to advise of the fact that appropriate testing was available at another institution nearby and failed to advise of the increased risk of misdiagnosis based on the samplings that were provided to Genesis, and NYU's failure to advise the Plaintiffs that the risks associated with utilizing the embryos that were chosen and the extent their studies increased the risk of an affected child. In this context, it should be recalled that, as Thornhill reported:

> …for compound heterozygous…conditions, the consequences of ADO [allele dropout] can be catastrophic, as misdiagnosis and subsequent transfer of affected embryos can occur. Indeed ADO is the most likely cause of reported errors in PGD of cystic fibrosis in which affected compound heterozygote embryos were misdiagnosed as carrier embryos because the analysis used could only detect one of the inherited mutations.
>
> (Pl. SUF, Para. 9)

In light of the known purpose that families use PGD analysis in preference to abortion, these Defendants certainly should have been able to foresee that, notwithstanding any disclosures made during prenatal testing, there would be no abortion and that the results of the Defendants' malpractice would be the birth of an affected child with serious disabilities. From the "final report" of Genesis, the plaintiffs, if informed of the deficiencies in the studies performed on their embryos by Genesis Genetics, had the

opportunity to provide further embryos in a further IVF procedure in which the genetic studies could have been properly performed before implantation. The distinguishing difference between the subject matter in the within case and the classic wrongful birth/wrongful life cases is the absence of an opportunity to terminate the pregnancy. Where PGD is involved the family has much greater control over the commencement of the gestation as opposed to situations where the deformity is not known until pregnancy is at least three to four months underway.

Can the law be so inflexible so as not to recognize the nuances of preimplantation genetic diagnosis, and deny those families who seek to undertake that process the opportunity to obtain a just result? This type of reasoning was the foundation for the New Jersey Supreme Court decisions in such cases as Berman v. Allan, 80 N.J. 421 (1979), and its progeny. By analogy, citing Gardner v. Pawliw, 150 N.J. 359, 387 (1997):

> When the prevailing standard of care indicates that a diagnostic test should be performed and that it is a deviation not to perform it, but it is unknown whether performing the test would have helped to diagnose or treat a preexistent condition, the first prong of Scafidi does not require that the plaintiff demonstrate a reasonable medical probability that the test would have resulted in avoiding the harm. Rather, the plaintiff must demonstrate to a reasonable degree of medical probability that the failure to give the test increased the risk of harm from the preexistent condition. A plaintiff may demonstrate an increased risk of harm even if such tests are helpful in a small proportion of

> cases. We reach that conclusion to avoid the unacceptable result that would accrue if trial courts in such circumstances invariably denied plaintiffs the right to reach the jury, thereby permitting defendants to benefit from the negligent failure to test and the evidentiary uncertainties that the failure to test created. See Scafidi, *supra*, 119 N.J. at 108, 574 A.2d 398; Evers, *supra*, 95 N.J. at 417, 471 A.2d 405.

Likewise, in the instant case, the legal rules were developed to avoid the unacceptable results that would accrue if trial courts in such circumstances invariably denied plaintiffs the right to reach a jury thereby permitting defendants to benefit from their negligent failure to appropriately test the embryo cells before implantation.

While this rationale should dispose of the other claims of Defendants, namely that the Plaintiffs are uncertain as to whether they would have rejected implantation if they were told that there was a 10 percent risk, the record indicates that if the Plaintiffs were told that there was a substantial risk greater than what Dr. Hughes had told them, they would have not likely gone through with the pregnancy. Chaya Grossbaum was specifically asked, "If Dr. Licciardi had said based on the interpretation of your particular embryos that you and your husband had a higher risk of having a CF baby than most PGD patients in your situation, then what would you have done?" Chaya Grossbaum answered, "I probably wouldn't have implanted the embryo." (Chaya Grossbaum Dep. 3/12/09 T:212-23 to 213-5;

NYU Exh. B.) The Plaintiffs clearly understood they had a minimum if any risk of a cystic fibrosis baby based on Dr. Hughes' communication. In light of this testimony, it is impossible for Defendants to succeed with a motion based on the cases cited with respect to wrongful life/wrongful birth.

In addition, Defendant NYU claims that the pregnancy and birth of the cystic fibrosis baby was more likely the result of the implantation of the embryo that had the least chance of being affected, namely Embryo No. 8. Both Dr. James Grifo (employee of Defendant NYU) and Dr. Samuel Pang (expert offered on behalf of Defendant NYU) are cited as offering such opinions on the ground that Embryo No. 8 was morphologically better than Embryo No. 7. However, their testimony is challenged by the testimony of Plaintiffs' expert, Dr. Charles Strom, who expressly disclaimed science allows one to determine which of the two embryos resulted in the pregnancy that brought forth the cystic fibrosis baby. (Strom Dep. 5/4/10 T:128-3 to 128-6; Pl. Exh. 7.) This argument of Defendant NYU is also challenged by the question: if it is unlikely that Embryo No. 7 would successfully result in a pregnancy, why did NYU choose to implant Embryo No. 7? Also, there was no scientific explanation as to why the fertility process would select one embryo over another based on the relative quality of the embryos. The sum and substance of the opinions by Dr. Grifo and Dr. Pang are net

opinions and are entitled to little weight in the first instance.

NYU'S SUMMARY JUDGMENT MOTION:
MORE FACT ISSUES

The processes by which in-vitro fertilization/PGD were undertaken by the patient at the NYU School of Medicine, Program for In-Vitro Fertilization, including PGD services are generally not in dispute. The family after an initial consultation with their doctor at NYU (in this case, Dr. Licciardi) is then referred to Dr. Mark Hughes to be advised with respect to laboratory analysis of their already known gene mutations for cystic fibrosis. After a period of hormone therapy to encourage the development of the female's eggs, and a sperm sample to prepare for the husband's insemination, the couple was ready for the removal of the egg, its fertilization through a needle procedure called ICSI with the sperm and, after a three day growth period, a single cell is biopsied from the collected fertilized embryos and sent to Detroit overnight for analysis. A report is then sent from the laboratory by Dr. Hughes advising as to which of the embryos if implanted would risk the delivery of an affected child. When the report is received from Dr. Hughes' laboratory, the patient is called into the fertility center for implantation of the embryo. At that time there is a consultation with the NYU doctor (Dr. Licciardi) regarding the

suitability of implanting the embryos based on information returned from the laboratory. The only genetic counselor that was involved with the patients prior to beginning the process and at the time that a decision is made to implant the embryos is the physician at NYU. In this case that physician was Dr. Licciardi. There are no steps in the process once the laboratory analysis is made for the patient to consult further with Dr. Hughes. In fact, Dr. Hughes had testified that as a practice he makes no further contact with the patient after the laboratory studies are made. (Hughes Dep. 5/14/10 T:28-4; Pl. Exh. 11.) This is a conscious and deliberate feature of the arrangement between the laboratory and the IVF Center. The only professional in the process and procedure to explain the results of the laboratory analysis was Dr. Licciardi. Any decision to be made regarding choosing the embryo to be implanted based on genetic analysis and viability of the embryo was Dr. Licciardi. Surely, there is no indication in the process that the husband and wife were expected to, or by any stretch of imagination, be able to make an intelligent decision regarding either the genetic suitability or the viability of the embryo.

Moreover, the form in which the information is transferred to the Fertility Clinic by the laboratory, that is Genesis Genetics and Dr. Mark Hughes, contains information about the results of the PCR testing on each of the embryo cells sent by

NYU. The results of the Genesis laboratory report must be understood by the IVF Clinic doctor, Dr. Licciardi, so that decisions could be made on implantation based on the genetic information contained in the report.

In this case, the record of the consultation between Dr. Licciardi and the Plaintiffs regarding implantation and the decision making that went into the decision to implant the embryos does not exist. (See Licciardi Dep. 3/11/09 T:52-21 to 53-6; NYU Exh. D.) Whether it ever existed cannot be established.

Discovery undertaken in an effort to determine Dr. Licciardi's medical reasoning for his decision-making in advising which embryos to implant, if any, revealed a distinct lack of understanding of the information conveyed by Genesis laboratory and the success of the laboratory evaluation of the cells from the embryos. (See Licciardi Dep. 3/11/09 T:49-7 to 49-8; 50-3 to 50-16; NYU Exh. D.)

An evaluation of Dr. Licciardi's participation at the clinic upon implanting the embryos revealed in his deposition that he had little or no understanding of PGD, of the shortcomings in the cells of the embryos that were analyzed in Detroit and further, that the Plaintiffs would encounter a significantly increased risk of having an affected child than would reasonably be expected under the state of knowledge at

that time. In particular, according to the expert opinion of Plaintiffs' expert, Dr. Garry Cutting, Dr. Licciardi showed no understanding of the single most significant factor to question the utilization of the embryos, namely allele dropout, because of the nature of the cystic fibrosis mutations contributed by each of the parents. They were compound heterozygous mutations. This lack of knowledge forms the basis of Plaintiffs' claim of malpractice by NYU. (See Plaintiffs' expert report of Dr. Garry Cutting; Genesis Exh. 24.)

The defense of NYU to these serious charges of malpractice is the claim that Dr. Licciardi is not competent nor is expected to be competent to evaluate the genetic component of IVF/PGD. As a physician trained as a reproductive endocrinologist, he is not expected to have a background in genetics sufficient to deal with the reports of the laboratory. Even though in this case Dr. Licciardi decided to disregard the "call" and insert a different embryo, inserting Embryo No. 7 instead of No. 10.

Thus, as the argument goes: don't blame me, it's the laboratory's responsibility to communicate the genetic suitability of the embryos for implantation. Of course, since the laboratory has no further communication with the patients, which professional involved in IVF/PGD at NYU was supposed to impart to the patients any increased risk or shortcomings found in the testing process based on the results of the tests

performed? Under which "shell" are the Plaintiffs supposed to find the critical explanations/questions involved in the decision making at the time of implantation? This in a nutshell is Plaintiffs' claim and reflects the deficiencies in the arguments made by Defendant NYU. In the least, the argument made is not one for summary judgment.

A.

NYU AND THE RISK OF MISDIAGNOSIS

Once again, Plaintiffs confront that aspect of their informed consent where they were told that there was a substantial risk of failure. NYU advertises a success rate "above 90 percent" which the Defendant juxtaposes to interpret as a misdiagnosis rate as high as 10 percent. But where are these statistics? They appear in the small print of the consent form at NYU which also states that they have had an experience with 60+ patients. (Genesis Exh. 13, CG091) On what basis? James A. Grifo, MD, described as NYU's director of PGD by Dr. Licciardi (Licciardi Dep. 3/11/09 T:28-15 to 18, Pl. Exh. 22), indicated in his deposition that he was aware of only one case of misdiagnosis during his more than 10 years at NYU and that one did not involve cystic fibrosis. (Grifo Dep. 6/24/09 T:8-22 to 9-14, Pl. Exh. 23). Also, Dr. Licciardi indicated that he was not aware of any situations involving misdiagnosis with respect to cystic fibrosis. (Licciardi Dep. 3/11/09 T:69-21 to

70-8, Pl. Exh. 22) We venture to suggest that if NYU had five or six misdiagnoses (10 percent of 60) doing PGD/IVF and harming that many fetuses, they would have closed up shop. Since there is no foundation for these statistics, it can only be understood to be an attempt to provide a defense to any claim that the Defendants may not have committed malpractice. Needless to say, there has been no literary support with statistical analysis that indicates that the Plaintiffs, who had well recognized cystic fibrosis mutations that according to Dr. Hughes "had been known for years," would carry that kind of statistical risk of misdiagnosis. This information is not too different from the form of surgical consents which patients are called upon to sign which indicate the risks of a routine spine operation may include paralysis or death. The law has long since established that it is no defense to malpractice that a patient may have been informed of the risks associated with the medical procedure.

PLAINTIFFS' EXPERT, DR. GARRY CUTTING:
QUALIFIED AND WITH OPINION THAT CHALLENGE NYU

In his report dated September 29, 2009 (Genesis Exh. 24), Dr. Garry Cutting, Professor of Pediatrics and Medicine, Director Post-Doctoral Training Program, Director DNA Diagnostic Laboratory at the Johns Hopkins University Institute of Genetic Medicine, stated:

> I have formed the opinion that there are two areas where Genesis Genetics and NYU IVF Clinic failed to offer a reasonable level of care. The first is in the counseling of the Grossbaums regarding alternatives for embryo transfer after it was discovered that the embryos recommended for transfer by Genesis Genetics were not suitable for transfer. Allele dropout (also known as ADO) is a well established source of error in preimplantation genetic diagnosis. From the deposition of Dr. Licciardi, it was apparent that he was not aware of this potential cause for error. Dr. Licciardi indicated during his deposition that he did not understand the results of the genetic testing results transmitted by Genesis Genetics. There is also no documentation of what was said during the counseling session between Dr. Licciardi and the Grossbaums regarding the risks of potential sources of error. Thus, Dr. Licciardi failed to adequately apprise the Grossbaums of the potential risks of using alternative embryos for transfer.

Dr. Cutting further stated in his report:

> It is reasonable to expect that Genesis Genetics would have offered multiplex DNA markers to minimize the risk of error due to ADO in the Grossbaums' case. If the laboratory was unable to offer this service, then the Grossbaums should have been informed so that they would have the option to select other services that offered PGD using multiplex markers.

In the least, this report from an expert of the professional level of Dr. Garry Cutting should require the Court to dismiss without pause the claims of the Defendants that there is no factual issue to be tried. Also, Dr. Cutting's *curriculum vitae* (included at NYU Exh. N) describes a physician of awesome training and accomplishment, which entitles him to be characterized as one of the world's leading experts in cystic

fibrosis. This Defendant's attempt to dichotomize the areas of specialty between Dr. Licciardi and NYU's Fertility Clinic and Dr. Cutting's record with cystic fibrosis as a clinician in a medical center is specious and unsustainable. Dr. Licciardi cannot hide behind his limited training as an endocrinologist when he is dealing with the genetics of PGD and serving as a genetic counselor to the patients at the NYU Fertility Clinic. This Court should see through this defense and also reject the notion that Dr. Cutting could not lend a helping hand to a factfinder in understanding the science of PGD and its application to patients in the IVF setting. Plaintiffs do not complain that any aspect of the IVF procedure, i.e. the hormone therapy prior to harvesting the embryos, the fertilization of the embryos with the sperm, the maintenance of the embryos and the implantation of the embryos to cause pregnancy is flawed. The issues in this case do not relate to the practices and processes of in-vitro fertilization. It is the genetic component of the in-vitro fertilization process involving PGD and the utilization of the laboratory information where fault is laid.

PGD is a service which NYU advertises it is providing at its Fertility Clinic. Nor should NYU be able to hide behind the self-serving statement of Dr. Mark Hughes as to the

responsibilities of the clinician with respect to PGD. With respect to the statement in the NYU brief at Page 11:

> Dr. Hughes, who recognizes that IVF practitioners do not, and are not expected to, understand genetics anymore than he understands IVF, and to the IVF practitioner, Dr. Licciardi, who recognizes the distinct areas of knowledge and expertise between himself and a geneticist such as Dr. Hughes…

How do those statements by Dr. Hughes and Dr. Licciardi supply this Court with sufficient information to declare that there is not a factual dispute?

STATUTE OF LIMITATIONS DEFENSE

As previously mentioned in our Preliminary Statement, Defendant Genesis raises a statute of limitations defense. It is predicated on application of the New Jersey discovery rule first announced in Lopez v. Swyer, 62 N.J. 267 (1973). It has since become an integral part of New Jersey jurisprudence. There is no dispute as to the legal principles to be applied. Two aspects of this defense should be noted. First, the Defendant seeks to invoke the Plaintiffs' "agreement" to undergo amniocentesis or CVS (chorionic villus sampling) analysis when the fetus is between 12 and 16 weeks old. It should not escape the Court that this is the third explanation for requiring the Plaintiffs to have amniocentesis or CVS studies. This argument of the Defendant proposes that the Plaintiff should undergo amniocentesis or CVS studies when: (1) there is no subsequent

intention to have an abortion; and (2) the Plaintiff has no awareness that there is any injury to her fetus which would suggest a need for further investigation of the status of the fetus at that time. Is this Defendant really urging the Plaintiff to undergo an invasive procedure such as the amniocentesis or CVS studies merely on the hypothetical basis that there may be malpractice which caused injury to her child? This argument by Genesis stretches beyond reason the application of the discovery rule.

While on the subject, it should be pointed out that Defendant Genesis through Dr. Hughes expressly disclaimed the purpose of the provisions in the consent requiring amniocentesis or CVS prenatal studies as being related to terminating the pregnancy. He stated that the sole purpose of that requirement is to allow information to assist in his research projects regarding the efficacy of the process of PGD. Dr. Hughes was asked:

> Well, what would be the purpose of doing an amnio and CVS test?

To which he answered:

> To find out the integrity of the single cell testing that we are doing on this project. As a scientist we have to be monitoring this.

He specifically denied that the purpose of doing CVS or amnio is to facilitate aborting a CF baby. (See Hughes Dep. 2/19/09 T:34-25 to 35-10; Pl. Exh. 6.)

Of course, when it appeared that there was a substantial increased risk of having an affected child from the laboratory studies that were performed at Genesis, Dr. Hughes changed his position and urged CVS and amniocentesis as a protection against the increased risk of getting an affected child. (See "Final Report" of Genesis; Pl. Exh. 10.) In any event, the clear import of the discovery rule would establish the date of Rosie's birth, her birth date being March 25, 2005, which comports with the requirements of the statute of limitations.

DEFENDANTS' MOTIONS TO STRIKE
PLAINTIFFS' EXPERT WITNESSES ARE FRIVOLOUS

The *curriculum vitae* of both Plaintiffs' experts, Dr. Garry Cutting and Dr. Charles Strom, have been provided to the Court. (See NYU Exh. N; Pl. Exh. 12.) Dr. Cutting's capacity to testify has been the previous subject of discussion in this brief and will not be repeated herein. Dr. Charles Strom can only be described as one of the pioneers and leaders in the field of preimplantation genetic testing commencing in the early 1990's to the current day. He was published widely on the subject of preimplantation genetic testing and especially with

the development of the technology to reduce the risk of allele dropout in the PCR gene analysis. His *curriculum vitae* demonstrates not only by education and experience, but by virtue of the extensive research and publications he has produced on molecular diagnostics of inheritable diseases right up to the present time. (See Strom *curriculum vitae* Items Nos. 99 to 103 through 2009; Pl. Exh. 12.) This suggests that Dr. Strom has at all times relevant to this case been involved in the subject matter of the litigation. Particular note is taken of the publication at No. 80.

In addition, not only have these Defendants misrepresented Dr. Strom's testimony about other IVF centers, but they have also setup their own standard as to what the measure of an expert witness' knowledge and experience is required to give testimony on such subjects as now before the Court. Aside from Dr. Strom's involvement in the development of the very processes of PGD studies in the decade between 1990 and 2000, he also indicates that he currently lectures on the university level on the subject of PGD. (See Strom Dep. 5/4/10 T:23-2 to 23-9; 24-6 to 24-8; Pl. Exh. 7.)

Rarely will the Court see the assemblage of such expertise on this high a level being presented in this matter on behalf of the Plaintiffs with the appearance of Dr. Garry Cutting of Johns

Hopkins and Dr. Charles Strom, now Medical Director of Quest Diagnostics' Genetic Testing Center.

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